14

Norplant, Depo-Provera and Progestin-Only Pills (Minipills)

"Ninety-five percent of our patients are using Depo-Provera" was the claim of a large Family Planning Association of Kenya (FPAK) clinic in northern Kenya in 1980. It took only a minute to discover why almost all the women obtaining contraceptives at this clinic were choosing birth control shots. Part of the answer was that there was no Depo-Provera at the surrounding Ministry of Health Clinics. The other reason for the tremendous popularity of Depo-Provera was the privacy it offered. Women could come to the FPAK clinic, obtain their shot every 3 months, and maintain their anonymity. No pills to take on a daily basis. No permit for a husband to sign before tubal ligation. No condoms or spermicides to wrestle with at the time of intercourse.

Any program offering Norplant, Depo-Provera, progestin-only pills, or a progestin-releasing intrauterine device (IUD) will be successful only if providers counsel women in advance about the menstrual changes that will occur when they use a progestin-only approach to contraception. Menstrual changes are the most common reason that women stop using these methods.

NORPLANT

When a woman decides to have Norplant implants inserted, this single decision may provide her with 5 years of effective birth control. At the time of insertion, it is important to assure the client that she can have the method reversed at any time by having the capsules removed.

DEPO-PROVERA

Depo-Provera, a form of depo-medroxyprogesterone acetate (DMPA) is the most commonly used injectable progestin. It is extremely effective in part because its protection continues even if a woman returns several days to 2 weeks late for an injection. DMPA has been used by more than 15 million women worldwide. It is approved for use in more than 90 countries.

MINIPILLS

Progestin-only pills are taken every day with no pill-free interval.

OVERCOMING BARRIERS

Injectable contraceptives have played an important role in Africa because of their availability and their long-term effectiveness and women's ability to use them discreetly. Norplant and progestin-only pills are not as widely used, largely because they are relatively unavailable. Education and counseling are the two greatest assets in overcoming barriers to the use of progestin-only contraception.

1. Bleeding irregularities are common among women who use progestin-only contraceptives. Women who are not aware of this side effect often discontinue use of the methods. Education and counseling allow women to realize that irregular bleeding is not harmful and does not indicate that the methods are not working.

2. Norplant implants are expensive initially. However, when distributed over the 5 years the implants remain in place, the cost per year is reasonable.
3. Norplant implants are sometimes implanted too deeply, making removal difficult and potentially hazardous. Proper training in both insertion and removal reduces this problem. Training in removal should cover several approaches, including the Emory method.[26]
4. An advantage of Depo-Provera injections is that they allow a woman to use a contraceptive without telling anyone else. Clinicians should be sympathetic to women placed in the position of needing to keep private their contraceptive use.
5. Because minipills have low doses of progestin, it is important they be taken every day at the same time.

MECHANISM OF ACTION

Progestin-only contraceptives may be administered by mouth, injection, or implants. The effects of these delivery systems are summarized in Table 14:1.[7] (Some IUDs also deliver progestin.) Progestin-only contraceptives may prevent pregnancy via several mechanisms:

- Inhibiting ovulation
- Thickening and decreasing the amount of cervical mucus (making it more difficult for sperm to penetrate)
- Creating a thin, atrophic endometrium
- Disrupting normal functioning of the corpus luteum (premature luteolysis)

NORPLANT

With this long-acting contraceptive, steroid levonorgestrel slowly diffuses through six slender, flexible capsules. Each of these match-sized capsules is 34 mm long and has a diameter of 2.4 mm. (See Figure 14.1.) Each capsule contains 36 mg of levonorgestrel, which is

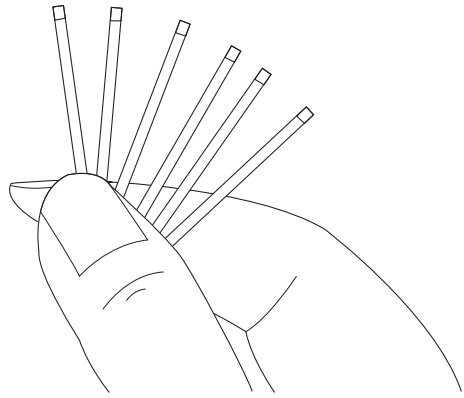
Table 14:1 Delivery systems for progestin-only contraceptives and combined oral contraceptives

	Progestin-Only			
	DMPA	**Norplant**	**Progestin-only pill**	**Combined OC**
Administration				
Frequency	Every 3 months	5 years	Daily	Daily
Progestin dose	High	Ultra-low	Ultra-low	Low
Blood levels	Initial peak then decline	Constant	Rapidly fluctuating	Rapidly fluctuating
First pass through liver	No	No	Yes	Yes
Major mechanisms of action				
Decreased ovulation	+++	++	+	+++
Decreased sperm penetrability	Yes	Yes	Yes	Yes
Decreased receptivity to blastocyst	Yes	Yes	Yes	Yes
First year failure rate	0.3	0.04	0.5	0.1
Menstrual pattern	Very irregular	Very irregular	Often irregular	Regular
Amenorrhea during use	Very common	Common	Occasional	Rare
Reversibility				
Immediate termination possible	No	Yes	Yes	Yes
By woman herself at any time	No	No	Yes	Yes
Median time to conception (from first omitted dose or removal)	6 months	1 month	<3 months	3 months

Sources: Adapted from Guillebaud (1985).

released at a low, steady rate of about 85 mcg per day, decreasing to 50 mcg at 9 months, 35 mcg at 18 months, and 30 mcg thereafter. When the capsules are removed, the contraceptive effect wears off quickly.

Figure 14:1 The 6-capsule Norplant system



DEPO-PROVERA

A deep intramuscular injection of 150 mg of DMPA is given every 3 months. DMPA injections inhibit ovulation by suppressing follicle stimulating hormone (FSH) and luteinizing hormone (LH) levels and eliminating the surge of LH. DMPA probably acts on the hypothalamus.[19] Each 150 mg injection actually provides more than 3 months of protection. A long-term user of DMPA has a 2-week "grace period" (longer in many instances) during which she can be late for her next shot but still not be at much risk of becoming pregnant.

MINIPILLS

In some women, minipills suppress ovulation. When this happens, the woman tends to be amenorrheic or have prolonged amenorrhea. If ovulation is not suppressed, these progestin-only pills have no effect on the cyclicity of bleeding, and menstrual bleeding occurs as it had before the woman started progestin-only pills. If ovulation does occur, the pills may still have a contraceptive effect because they cause thickening of the cervical mucus.

EFFECTIVENESS

NORPLANT

Norplant failures are rare. In the first year of use, 0.2% users experience a pregnancy.[30,37] If women already pregnant when the device was implanted are removed from this calculation, the pregnancy rate falls to 0.09%. To avoid using this contraceptive in women who are already pregnant, clinicians should insert implants within 7 days of the onset of menstruation or, for women who have just delivered, either immediately postpartum or within 3 weeks after delivery.

Pregnancy rates for the second through fifth years are, respectively, 0.5%, 1.2%, 1.6%, and 0.4%. After 5 years, the total (cumulative) pregnancy rate is therefore only 3.7%.

Because pregnancies increase in the sixth year, women should have the capsules removed at the end of the fifth year. (Norplant is approved as a 5-year method.) If a woman wishes to continue using Norplant, she can have another set of implants inserted at the same time the first set is removed.

Women who weigh more than 70 kg may have higher pregnancy rates. However, most pregnancies in overweight Norplant users have been in women who were provided the hard capsule Norplant implants. Leiras Oy, the manufacturer, now produces implants only with the new soft tubing.[18]

Continuation rates for Norplant users are high; reported first-year continuation rates range from 85% to 95%.[1,13,30] In five studies from around the world, 33% to 78% of users completed 5 years on Norplant.[18]

DEPO-PROVERA

Depo-Provera is an extremely effective contraceptive with a first-year probability of pregnancy of only 0.3%. This pregnancy rate applies to women receiving injections providing 150 mg of DMPA in 1 cc of solution.

Questions have been raised about the desirability of giving injections of 150 mg of DMPA every 3 months when DMPA can be given in much less expensive solutions that provide 400 mg of DMPA per 1 cc of this medication. (With this alternative, only 0.375 cc of solution is required to deliver 150 mg of DMPA.) However, it is very difficult to provide exactly 150 mg of DMPA in such a small amount of solution (0.37 cc), and this way of delivering DMPA is not approved as a contraceptive. Another approach would be to give 400 mg every 6 months in 1 ml of the 400 mg/ml formulation, but an unpublished Upjohn-sponsored trial of this alternative found that pregnancies occurred throughout the 6-month treatment period, not just at the end.[2] The concentrated form of DMPA is also more painful. Pain has been overcome by diluting the very concentrated form of DMPA with an equal volume of 1% xylocaine.

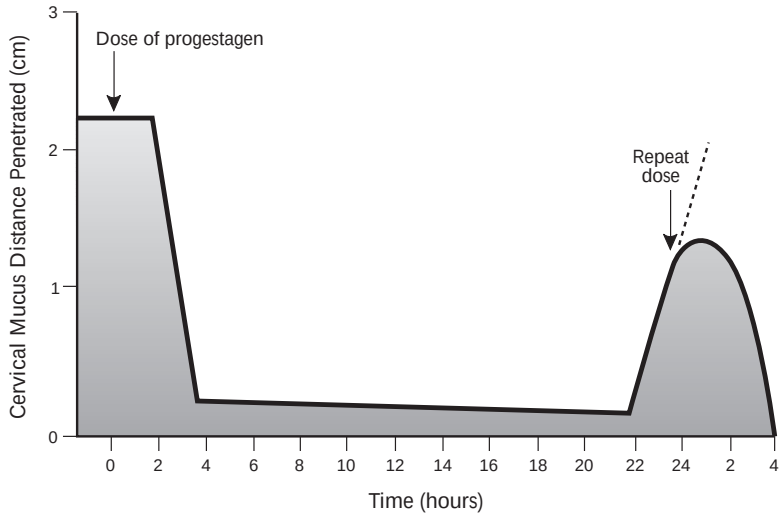
In the largest study of U.S. women, continuation rates for women on DMPA were 59.4%, 41.5%, 30.2%, 24.1% at 1, 2, 3, and 4 years, respectively.[27]

MINIPILL

Progestin-only pills are generally less effective than combined oral contraceptives (OCs). The proportion of women becoming pregnant in the first year of typical use ranges from 1.1% to 13.2%. If minipills were used correctly and consistently; however, only 5 in 1,000 (0.5%) women would become pregnant in the first year.

The effectiveness of progestin-only pills is highest when ovulation is consistently inhibited. When this happens, a woman tends to be amenorrheic or to have prolonged periods of time between menstrual bleeding episodes. *The effectiveness of progestin-only pills is greatest when the "normal" bleeding pattern is most disturbed.* It is particularly important that progestin-only pills not be taken even a few hours late, because they will then lose effectiveness. Figure 14:2 illustrates how the sperm penetration of cervical mucus increases if the time interval between progestin-only pills is more than 24 hours. In breastfeeding women, the progestin-only pill is nearly 100% effective.[7]

Figure 14:2 Sperm penetration test following progestin-only pill



Note: Minimum reduction in sperm penetration between 4 hours and 22 hours after a single dose of megestrol acetate (0.5 mg). Unlike the rest of the figure, the effect of a repeat dose is presumed, not experimental.

Source: Guillebaud (1985).

ADVANTAGES AND INDICATIONS

ADVANTAGES

The following advantages hold for all progestin-only contraceptives.

1. No estrogen. Because progestin-only contraceptives contain no estrogen, they do not cause the serious complications associated with estrogen, which include thrombophlebitis and pulmonary embolism. Studies thus far have not shown any serious short-term or long-term effects of DMPA.[5,6,20,28]
2. Noncontraceptive benefits. Norplant, Depo-Provera, and progestin-only pills offer several noncontraceptive benefits:
   - Scanty menses or no menses
   - Decreased anemia
   - Decreased menstrual cramps and pain

- Suppression of pain associated with ovulation (mittelschmerz)
- Decreased risk of developing endometrial cancer, ovarian cancer, and pelvic inflammatory disease (PID)
- Management of pain associated with endometriosis

3. Reversibility. Norplant and minipills are immediately reversible. A woman must use alternative forms of contraception as soon as Norplant implants are removed or minipills are stopped. Depo-Provera is reversible, but return of fertility is not as rapid as with Norplant or progestin-only pills.[23] There is a delay in return of fertility of an average of 6 months to 1 year after ceasing use of Depo-Provera.[34] No surgical procedure is necessary to discontinue use of Depo-Provera or progestin-only pills.
4. Long-term effective contraception. Norplant implants and long-acting injections are extremely effective long-term contraceptives. In the case of Norplant (and the levonorgestrel IUD), a single decision leads to long-term contraception. The effectiveness of implants and injections does not depend on the woman's taking day-to-day responsibility for her contraception. DMPA provides excellent short-term contraception for women who require protection following rubella immunization, are awaiting sterilization, or are partners of men undergoing vasectomy. Women appearing late for their injection of DMPA have a grace period during which they will not become pregnant. The package insert defines this period as 2 weeks; others suggest that the grace period is 4 weeks.
5. Low risk of ectopic pregnancy. Norplant and DMPA reduce a woman's risk of having an ectopic pregnancy compared to women using no contraceptive at all. Women using Norplant have an ectopic pregnancy rate of 1.3 per 1,000 woman—versus the 6.5 per 1,000 women-years for women using no contraceptive. Ectopic pregnancy may be more common in heavier women or may increase with longer use of Norplant.[18] Ectopic pregnancy is very unlikely to occur in women receiving DMPA injections. Progestin-only pills are less protective against ectopic pregnancies than are combined pills, Norplant, or DMPA.

6. Amenorrhea. Progestin-only contraceptives cause amenorrhea in some women, but some users may consider the absence of bleeding an advantage. During the first year of DMPA use, 30% to 50% of women are amenorrheic; by the end of the second year, 70% are amenorrheic, and by the end of the fifth year, 80% are.[20] In contrast, amenorrhea occurs less frequently in women using Norplant.

NORPLANT

7. Continuation rates. Norplant has higher continuation rates than do other hormonal contraceptives. The percentage of women continuing to use Norplant at 1 year is 85%. The continuation rate is about 15% less for women using pills or Depo-Provera.
8. Not coitus dependent. Norplant (and to a lesser extent, long-acting injections) is an excellent contraceptive option for women who have difficulty remembering to take pills or in using methods requiring interruption of intercourse. For example, Norplant may be a good option for a woman who abuses drugs or will have difficulty taking pills but who definitely wants to avoid pregnancy.

DEPO-PROVERA

9. Culturally acceptable. In some cultures, women consider receiving medications by injection to be desirable. For some women, it is a desirable option to be able to use a contraceptive without the knowledge of her partner, husband, or family.
10. No drug interaction. Thus far, there has been no demonstrated interaction between Depo-Provera and antibiotics or enzyme-inducing drugs.[34] DMPA effectiveness does not depend on a normally functioning gut.
11. Fewer seizures. DMPA has been found to decrease the frequency of seizures among women of childbearing age.[15]

MINIPILLS

12. Ease of use. Because using the minipill means taking the same type of pill every single day (same color and hormone content), some women may find it easier to use this kind of pill than other OCs.
13. Emergency contraception. An emergency dosing of minipills—0.75 mg progestin taken within 48 hours of unprotected intercourse and another dose of 0.75 mg taken 12 hours later—can reduce the risk of unintentional pregnancy. A pill called Postinor, available in Europe and Asia, delivers each 0.75 dose in one pill. All other minipills, which contain far less progestin, require that 20 pills be taken to equal the 0.75 mg dose. One dose of 20 minipills is taken within 48 hours after intercourse and a second dose of 20 pills is taken 12 hours after the first dose. (See Chapter 13 on Combined Oral Contraceptives for more discussion on "Emergency Contraceptive Pills.")

INDICATIONS

Breastfeeding Women

Norplant, Depo-Provera, and minipills do not harm lactation, and some studies suggest that milk volume may increase.[12,16] Although progestins can pass through breast milk, the dose ingested by the infant is small. Opinions vary about whether Norplant and Depo-Provera should be provided immediately postpartum. A cautious approach is to wait until breastfeeding has been well established. (See Chapter 12 on Lactation and Postpartum Contraception.)

Norplant. If a breastfeeding woman is unlikely to return for a postpartum visit and requests Norplant before leaving the hospital after delivery, the real long-term contraceptive benefit of using this method seems likely to exceed its theoretical risks, especially if the woman plans to supplement the infant's diet relatively soon after birth.

Depo-Provera. Studies of Depo-Provera started 2 to 4 days postpartum or at 7 days postpartum,[16] and within 6 weeks postpartum[12] have all found no negative effects. Because the contraceptive benefit to the lactating woman in obtaining Depo-Provera immediately postpartum is smaller and the theoretical risks might be higher (hormonal levels are relatively high in the immediate post-injection days) than those for Norplant, it would be less advisable to inject Depo-Provera than to insert a Norplant before breastfeeding is well established.

Minipills. Studies of minipills have demonstrated no adverse effects on lactation or infant growth, even when they are started in the first week postpartum.[17,21]

Older Women

Safety and low pregnancy rates make Norplant, Depo-Provera (and other long-acting injections), and progestin-only pills good options for older women. A woman may have Norplant inserted when she is fairly certain she wants no more children. Then, after 3 to 4 years, when she is absolutely certain she wants no more children, she may choose to have a tubal ligation or her husband may decide to have a vasectomy, followed by Norplant removal. For a woman who will be deciding about sterilization in the next 3 to 12 months, DMPA may be a better option than Norplant. Progestin-only pills are also an excellent option for women who are in their late reproductive years; they are more effective for older women.[3] The absence of complications from thrombosis makes Depo-Provera, Norplant, and progestin-only pills advantageous for older women and for women planning to have an operation that might increase their risk for thrombophlebitis.

Young Women

For younger women, Norplant is desirable because of its extremely low pregnancy rate and its ready reversibility. The thick cervical mucus produced by implants also protects against PID. Depo-Provera is less readily reversible, but it has a very low pregnancy rate and probably protects against PID.

Women Who Cannot Take Estrogen

Progestin-only pills, as well as the other progestin-only methods, are particularly desirable for women who want to use an OC but have reasons to avoid combined pills. Women who have developed severe headaches or hypertension may be candidates for progestin-only pills.

DISADVANTAGES AND PRECAUTIONS

The progestin-only methods have few serious disadvantages. The precautions for prescribing are listed in Table 14:2.

1. Menstrual cycle disturbance. One of the most common reasons women stop using progestin-only contraceptives is that these methods change the menstrual cycle. Many women experience an increased number of days of light bleeding. Some women experience amenorrhea, which is most likely to occur in the first year of Norplant use. *While missed menstrual periods become less common over time among women using Norplant, amenorrhea becomes more common over time in Depo-Provera users.* Occasionally, women using Norplant or DMPA experience an increased number of days of heavy bleeding. Bleeding changes are usually *not* associated with increased blood loss in users of progestin-only contraceptives. Counsel women to expect changes in their cycles.
2. Weight gain. Some women using progestin-only methods gain weight or complain of feeling bloated. The weight gain is probably due to increased appetite stimulated by progestin rather than fluid retention.[34] Over 5 years, weight gain in Norplant users averages just under 5 pounds. Weight gain is less of a problem in women on progestin-only pills than in women on combined OCs.
3. Breast tenderness. Breast tenderness, which is occasionally very painful, has been noted in some women using Norplant and Depo-Provera. Always rule out pregnancy as the cause.
4. Interaction with anticonvulsants. Anticonvulsants (except valproic acid) increase Norplant pregnancy rates and, probably, pregnancy rates for progestin-only pills.

5. Bone density decrease. Decreased bone density has been reported in a retrospective study of 30 Depo-Provera users.[4] One confounding effect in the study was that the DMPA users (40%) were more likely to smoke than were the premenopausal control women (10%). Although this one study does not mean that women should avoid long-term use of DMPA, the results suggest that osteoporosis and other effects of low estrogen need to be carefully considered.
6. Lack of protection against sexually transmitted infections (STIs), including HIV. No matter what other methods of contraception a woman is using, if she is at any risk because her partner is HIV positive or because she does not know her partner's HIV status, she should be advised to use condoms with every sexual act. No other contraceptive method besides abstinence provides the same degree of protection.

Norplant

7. Difficulty in removing Norplant. Both insertion and removal require a minor surgical procedure. Removal is particularly likely to be difficult if the implant was inserted too deeply. Norplant removal requires a clinic visit and, occasionally, more than one visit.
8. Expense. The initial cost of Norplant can be high, and if the implants are removed soon after insertion, this method is extremely expensive per month of contraception provided. Encourage long-term use by doing the following:
    - Explaining, in advance, the menstrual cycle changes that are likely to occur
    - Avoiding Norplant insertion for the woman who may change her mind quickly and want to become pregnant in the near future
    - Avoiding insertions for women who are already pregnant

Table 14:2 Precautions in the provision of progestin-only contraceptives (POCs)

Condition	Category			Rationale/Comments
	Mini pill	DMPA	Nor-plant	
Pregnancy	4	4	4	As no method is indicated, any health risk is considered unacceptable. However, the evidence on the possible harm to mother and fetus is incomplete.
Breastfeeding				
<6 wks postpartum	3	3	3	Concern that immature neonate may be at risk for exposure to steroid hormones.
>6 wks to 6 mths postpartum (primarily breastfeeding)	1	1	1	No concern regarding use of POCs in breastfeeding mothers after 6 weeks postpartum.
>6 mths postpartum	1	1	1	
Age				
Menarche—age 16	2	2	2	For women under 16 years of age, concerns regarding hypoestrogenic effect
>Age 40	1	1	1	due to POC use.
Smoking	1	1	1	No concern regarding risk of thrombosis with POC use.
Essential hypertension				
Mild hypertension (<180/105)	1	2	1	Concern regarding reduced high density lipoproteins in women using DMPA and Norplant with underlying vascular disease or moderate and severe hyper-
Moderate and severe hypertension	1	2	1	tension.
Vascular disease	2	3	2	
History of preeclampsia	1	1	1	Absence of underlying vascular disease suggests no need for restriction of POC use.
Diabetes				
History of gestational disease	1	1	1	
Non-vascular disease:				
non-insulin dependent	2	2	2	POC may influence carbohydrate metabolism, but does not present an additional risk of thrombosis.
insulin dependent	2	2	2	

1 = used in any circumstances
2 = generally used
3 = usually not used unless other more appropriate methods are not available or acceptable
4 = not to be used

Table 14:2 Precautions in the provision of progestin-only contraceptives (POCs) (Continued)

Condition	Category			Rationale/Comments
	Mini pill	DMPA	Nor-plant	
Nephropathy/retinopathy	2	3	2	Concern about possible negative effect of DMPA on lipid metabolism, possibly affecting the progression of nephropathy, retinopathy, or other vascular disease.
Other vascular disease or diabetes of >20 years' duration	2	3	2	
Venous thromboembolism				
Current and history	1	1	1	
Major surgery				
with prolonged immobilization	1	1	1	No concern regarding risk of thrombosis in POC users.
without prolonged immobilization	1	1	1	
Minor surgery without immobilization	1	1	1	
Varicose veins	1	1	1	
Superficial thrombophlebitis	1	1	1	
Current and history of ischemic heart disease	2	3	3	Concern regarding hypoestrogenic effect and reduced high density lipoproteings (HDL).
Stroke				
Current (in hospital)	3	3	3	Concern regarding reduced HDL among POC users.
History	2	3	2	
Familial hyperlipidemia	1	2	1	Although these conditions are a risk factor for vascular disease, routine screening is not needed and is inappropriate because of rarity of the condition and cost of screening.

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Table 14:2 Precautions in the provision of progestin-only contraceptives (POCs) (Continued)

Condition	Category			Rationale/Comments
	Mini pill	DMPA	Nor-plant	
Valvular heart disease				
Uncomplicated	1	1	1	No concern regarding risk of thrombosis in POC users.
Complicated (pulmonary hypertension, risk of arterial fibrillation, history of subacute bacterial endocarditis)	1	1	1	
On anticoagulant drugs	2	2	2	POC use may be associated with prolonged bleeding in the first three months. It is unknown if anticoagulants aggravate the bleeding.
Headaches				
Mild	1	1	1	No concern regarding risk of thrombosis in POC users.
Severe:				
recurrent, including migraine, *without* focal neurologic symptoms	1	2	2	Theoretical concern that severe headaches may increase in frequency; DMPA and Norplant cannot be discontinued immediately or effects persist for sometime after discontinuation.
recurrent, including migraine, *with* focal neurologic symptoms	2	2	2	
Irregular menstrual patterns (cyclic pattern maintained)				
Without heavy bleeding	2	2	2	Changes in menstrual bleeding patterns are common among healthy women.
With heavy bleeding	2	2	2	POC use may induce irregular bleeding pattern.
Unexplained vaginal bleeding (cyclic pattern disrupted)	3	4	4	Evaluation of these conditions is necessary before initiating POC.

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4 = not to be used

Table 14:2 Precautions in the provision of progestin-only contraceptives (POCs) (Continued)

Condition	Category			Rationale/Comments
	Mini pill	DMPA	Nor-plant	
Breast disease				
Undiagnosed mass	2	2	2	
Benign breast disease	1	1	1	No concern related to POC use for women with benign breast disease or family history of breast disease.
Family history of cancer	1	1	1	
Cancer:				
current	3	4	4	Breast cancer is a hormonally sensitive tumor. Concerns may be less with POC than with combined pills.
past and no evidence of current disease	3	3	3	
Cervical intraepithelial neoplasia (CIN)	2	2	2	Little concern that POC enhances progression of CIN to invasive disease.
Cervical cancer (awaiting treatment)	2	2	2	Theoretical concern that use may affect prognosis of the existing disease.
Cervical ectropion/erosion	1	1	1	Not a risk factor, no need for restriction of POC use.
Endometrial, ovarian cancer	1	1	1	In general, treatment of these conditions renders a woman sterile. While awaiting treatment, women may use POC.
Pelvic inflammatory disease (PID)				
Past (assuming no current risk factors of STIs)				
with subsequent pregnancy after past PID	1	1	1	
without subsequent pregnancy, however, pregnancy is desired	1	1	1	
without subsequent pregnancy, and pregnancy is not desired	1	1	1	Not a concern, no need for restriction of POC use.

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Table 14:2 Precautions in the provision of progestin-only contraceptives (POCs) (Continued)

Condition	Category			Rationale/Comments
	Mini pill	DMPA	Nor-plant	
Pelvic inflammatory disease (PID) — c*ontinued*				
Within the last 3 mths	1	1	1	
Purulent cervicitis	1	1	1	
Trachomatis or N. Gonorrhoea	1	1	1	
Vaginitis without purulent cervicitis	1	1	1	
Increased risk of STIs (e.g. multiple partners or partner who has multiple partners)	1	1	1	
STIs: current or within 3 months	1	1	1	Not a concern, no need for restriction of POC use.
HIV/AIDS				
HIV+	1	1	1	No confirmation of an association of POC use with these conditions, although a modest risk may be present.
High risk of HIV	1	1	1	
AIDS	1	1	1	
Biliary tract disease				
Symptomatic				
surgically treated	1	1	1	Not a concern, no need for restriction on POC use.
medically treated	1	1	1	
current	1	1	1	
Asymptomatic	1	1	1	
Sickle cell disease	1	1	1	
Epilepsy	1	1	1	The condition, *per se*, is not a concern. No need for restriction of POC use. Certain antiepileptic drugs lower POC efficacy. If a women is taking treatment, refer to section of drug interactions.

1 = used in any circumstances
2 = generally used
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4 = not to be used

Table 14:2 Precautions in the provision of progestin-only contraceptives (POCs) (Continued)

Condition	Category			Rationale/Comments
	Mini pill	DMPA	Nor-plant	
Schistosomiasis	1	1	1	Not a concern, no need for restriction of POC use.
Malaria	1	1	1	Not a concern, no need for restriction of POC use.
Drug interactions				
Commonly used drugs with affect liver enzymes: antibiotics (rifampicin and griseofulvin)	3	2	3	Commonly used liver enzymes inducers are likely to reduce the efficacy of POCs.
anticonvulsants (phenytoin, carbamezapine, barbiturates, primadone)	3	2	3	Use of other contraceptives should be encouraged for women who are on long-term use of any of these drugs.
Other antibiotics*	1	1	1	
Parity				
Nulliparous	1	1	1	Not a concern. No need for restriction of POC use.
Parous	1	1	1	
Rapid return to fertility desired	1	3	1	Some delay in return to fertility may occur with DMPA use (10 months median delay in conception after last DMPA injection). No risk for permanent infertility.
Severe dysmenorrhoea	1	1	1	Not a concern. No need for restriction of POC use.

*Excluding rifampicin + griseofulvin
1 = used in any circumstances
2 = generally used
3 = usually not used unless other more appropriate methods are not available or acceptable
4 = not to be used

Norplant (continued)

9. Extremely low-dose contraceptive. Because of its low dose, Norplant's effectiveness is lowered more significantly by anti-seizure medicines (except for valproic acid) and by rifampin than are other hormonal contraceptives. Norplant pregnancy rates increase to unacceptable levels if a woman takes any of the following drugs:[8,22]

carbamazepine	primidone
phenytoin (Dilantin)	phenylbutazone
phenobarbital	rifampin

   All anti-seizure medications are strong inducers of the hepatic enzymes, which cause breakdown of levonorgestrel. If a Norplant user begins one of these medications, she should use a back-up contraceptive.

10. Local inflammation or infection at the site of implants. First-year users occasionally have infection, skin irritation, or expulsion of a capsule, but complications do not always occur immediately after insertion. One-third of infections and two-thirds of expulsions occur after the first 2 months of use.[11]

11. Ovarian cysts. Most ovarian cysts regress spontaneously. Cysts do not need to be evaluated sonographically or laparoscopically unless they become large, painful, or fail to regress.[36]

Depo-Provera

12. No immediate discontinuation. Weight gain, depression, breast tenderness, and menstrual irregularities may continue until the DMPA is cleared from a woman's body—about 6 to 8 months after her last injection. A woman becomes fertile again in an average of 6 months to 1 year after ceasing to use Depo-Provera.[34]

13. Return visits every 3 months. Some women find the requirement of repeated injections unacceptable. However, most women continue to use DMPA after 1 year.

14. Lipid changes. High-density lipoprotein cholesterol levels fall significantly in women using DMPA.[20] Adverse changes in lipids do not occur in women using Norplant.

Minipills

15. Vulnerable efficacy. Progestin-only pills require absolute regularity in pill-taking and attention to timing.

16. Less available. These pills are less likely than OCs to be stocked by pharmacies, family planning clinics, and hospital formularies.

17. Less clinician experience. Clinicians are less likely to have had experience prescribing progestin-only pills and may be less comfortable in counseling patients about them.

18. Ovarian cysts. Minipill users experience an increased risk of functional ovarian cysts. See the discussion of ovarian cysts under the section on Norplant.

19. Ectopic pregnancy. Ectopic pregnancy is more likely among women who become pregnant as a result of minipill failure than among women who use other OCs.

PROVIDING NORPLANT

Although Norplant implants produce few side effects or complications, some women are not ideal candidates. Table 14:3 describes the precautions for providing Norplant implants. These precautions replace the outmoded concept of contraindications.

Although hormonal methods are not considered the method of choice for breastfeeding women. Norplant implants may still be appropriate for this group. (See the section on Indications in this chapter and the discussion in Chapter 12 on Lactation and Postpartum Contraception.)

Table 14:3 Percentage of women reporting regular bleeding patterns or amenorrhea while using Depo-Provera injections Norplant implants

	Depo-Provera		Norplant	
	1 year	**5 years**	**1 year**	**5 years**
Regular cycles*	30	17	27	67
Amenorrhea	25	80	5	9

*Regular cycle is 25 to 34 days for Depo-Provera users and 21 to 35 days for Norplant users.

Source: Shoup, et al. (1993)

NORPLANT INSERTION: 20 HELPFUL HINTS

Norplant insertion is a minor surgical procedure performed under local anesthesia. Using a simple trocar, the clinician places the implants under the skin on the inside of a woman's upper arm in a fan-shaped configuration. Norplant implants should be replaced after 5 years. A two-capsule Norplant system is being developed to simplify both insertion and removal.

1. Use an arm model to practice insertion. If this is the first, second, or third time you have inserted Norplant implants, take 3 to 5 minutes to insert a set of implants into the arm model. Practicing on the model will remind you what to do and what not to do.
2. Reassure your new client that insertion is not painful. Fear of pain at the time of insertion is the number one concern of women considering Norplant.
3. Raise the head of the examination table to make your patient more comfortable.
4. Use the width of 4 fingers if you are a man, or 5 fingers if you are a woman, to measure up from the crease of the elbow to the place where you will make your incision. Mark this site using a template and pen.

5. Use the template and pen every time you insert a set of Norplant implants. Make no exceptions. These marks will help you put your local anesthetic at the precise site your trocar will be placed. This precision will also make removals easier, because you will know where to look for the implants.
6. Add sodium bicarbonate to the local anesthetic to decrease stinging as the local anesthetic is injected into the insertion sites. Use 0.5 cc of sodium bicarbonate ($NaHCO_3$) for every 5 cc of 1% xylocaine (a 1:10 ratio). Xylocaine comes in a 30 cc bottle. With 3 cc of $NaHCO_3$ added, you will have enough local anesthetic for a number of Norplant insertions in a single session. Throw away any remaining anesthetic at the end of each insertion session, because the $NaHCO_3$ destabilizes the xylocaine over time. Mix up only as much of the 1:10 solution you will need in a day.
7. Inject the local anesthetic slowly so that the patient feels less discomfort. A slow injection is particularly helpful if you are injecting xylocaine with no sodium bicarbonate. By the time the injection has been made for the sixth implant, the local anesthesia will be almost ready for the incision to be made.
8. Save 1 cc of local anesthetic for the sixth implant insertion site. If the anesthetic runs out, the client may experience significant pain during insertion of the last implant.
9. Make the incision very small—about 2 to 3 mm. With a small incision, the scar will be smaller. It is possible to make the incision with the trocar itself with no increased risk of pain, tenderness, edema, ecchymosis, or extensive scarring. Making a small incision with a scalpel makes introducing the trocar easier.
10. Insert the implants superficially in the tissue—this is the most important goal of the entire insertion process. Implants inserted deeper in the tissue layers are more difficult to remove.
11. Do not move the inner plunger as you withdraw the outer part of the trocar. Do not push on the inner plunger with your thumb or retract the inner plunger. The plunger should remain fixed.

12. Allow the trocar to remain inside the incision (under the skin) between insertion of each individual implant.
13. Once you have inserted an implant, hold it in place while you advance the trocar to insert the next implant. By holding the implant in place, you will prevent the trocar from catching and misplacing an already inserted implant.
14. Locate the distal tips of all six implants following insertion. If one implant is 5 to 10 mm farther from the incision than the others, it is often possible to push that implant with your fingernail toward the incision before wrapping the arm. Doing so will simplify removal.
15. Gently clean the area with an alcohol swab before bandaging your client's arm.
16. Show the client the incision site before you put on the butterfly bandage or gauze. She will be reassured when she sees the very small incision.
17. Roll the gauze or bandage over a 4"x 4" folded pad. Do not wrap it too tightly. Suggest that your client leave the gauze wrapping on the arm for 3 to 5 days to avoid having people touch the area while it is still tender.
18. Warn your client that she may have a large bruise when her bandage is removed. Tell her that the bruise will change colors before going away completely.
19. After insertion, inform the client whether an implant has been inserted too deeply or too far, or whether the proximal end of one implant was pulled distally.
20. After insertion, provide your phone number to your client and encourage her to call if she has questions or problems. Remind her that Norplant will cause a change in her menstrual cycle and that she should call if her new pattern of bleeding is bothersome. Remind her that medications can improve a bothersome pattern of bleeding.

NORPLANT REMOVAL: 20 HELPFUL HINTS

1. Use the arm model to practice removal. Wyeth Laboratories provides a plastic sheathing into which the implants are placed. The clinician may practice cutting the plastic sheath to remove implants.
2. If possible, perform your first Norplant removal with someone at your side who has experience removing Norplant implants. **Schedule adequate time**. Your first few removals may take 45 to 60 minutes. As you gain experience, the time of removal decreases to 20 to 30 minutes.
3. Try the Emory method of Norplant removal to ease the procedure. Some clinicians average less than 15 minutes per removal by using the following three techniques:[26]
   - Using 6 to 8 cc of local anesthesia rather than 3 cc
   - Making an 8 to 10 mm incision rather than a 4 mm incision
   - Vigorously disrupting adhesions for 30 seconds by repeatedly opening a small curved hemostat in the tissue near the end of the implants before attempting removal of implants[27]
4. Remind the client that removal may be more difficult than insertion. Inform her that removal may take 30 or more minutes and could require a second visit.
5. Raise the head of the exam table to make the patient more comfortable.
6. Be sure you are comfortable as you begin the removal. You may be more at ease sitting rather than standing and leaning over the patient's arm.
7. Identify both the proximal and distal end of each of the six implants. Mark the ends with a pen.
8. Add sodium bicarbonate to the local anesthetic to decrease stinging. This procedure is described in suggestion #6 in the previous section on Norplant insertion.
9. Inject the local anesthetic slowly under the proximal one-third of the implants. Wyeth instructions recommend that you initially

inject about 3 cc of 1% xylocaine. Have another 3 to 5 cc of xylocaine available to provide additional anesthesia in case you need it later. An alternative approach is to inject 8 to 10 cc of local anesthesia to permit a longer incision (1 cm) and more vigorous breaking up of adhesions with a small curved hemostat.[26]

10. Rather than making your incision at exactly the same site as the location of the incision used to insert implants, make the incision 3 to 5 mm above the original incision site. Doing this makes the removal incision closer to the proximal tips of the six implants.
11. Make the incision for removal a bit longer (5 to 10 mm) than the incision used for insertion.
12. Make a second incision if one implant is far from the other implants.
13. Throughout the procedure, ask the client whether she feels any pain. Provide additional local anesthetic if needed.
14. Have an assistant help during the removal procedure.
15. With your finger, apply pressure to the distal end of each implant as you remove it. Push the implant toward the incision.
16. With a sharp blade or a gauze pad, remove the scar tissue covering the implants.
17. Do not pull an implant too hard; it may break.
18. Warn your client that she may develop a bruise after removal, but tell her it will go away completely.
19. Advise your client that taking a prostaglandin inhibitor may be helpful if she has pain in her arm after implant removal.
20. Remind your client that she may become pregnant immediately following Norplant removal. If she does not want to become pregnant, discuss contraception.

MANAGING NORPLANT PROBLEMS AND FOLLOW-UP

A number of side effects may occur in women using Norplant implants. Table 14:4 lists the side effects that were more common in women using Norplant than in women using an IUD.[18]

Various treatments can improve these symptoms. Occasionally, the implants must be removed to eliminate these complications. The physiological basis of many Norplant side effects needs clarification and it is an important research priority.

Menstrual disturbances. Changes in the pattern of menstrual bleeding are a common reason for removing Norplant implants, but counseling can minimize decisions to remove implants because of this side effect. Inform women in advance to expect a change in the pattern of bleeding; more than 80% of women will notice a change.[16,29] The three most common new patterns are an increased number of days of very light bleeding, amenorrhea, and increased days of heavy bleeding. The third pattern is not common. Inform women that several medications can help with these bothersome patterns of bleeding. It is very reassuring for women to know about these symptoms and that something can be done about them before the first sign of a bleeding problem appears. Clinicians may find several therapeutic approaches helpful:

- Several cycles of a low-dose combined OC
- Use of prostaglandin inhibitors
- Exogenous estrogens such as oral 17b estradiol (Estrace), ethinyl estradiol (Estinyl), or conjugated estrogens (Premarin)

Be sure to inform women that the irregular pattern of bleeding may return when treatment is stopped.

Headaches. Headaches may be associated with pregnancy and with use of OCs and Norplant implants. If severe headaches associated with blurred vision and papilledema develop as a new symptom following Norplant insertion, removal of implants may need to be done

quickly. In December 1992, Wyeth Laboratories sent a letter to physicians describing severe headaches, papilledema, and a pseudotumor cerebri-like syndrome in 14 women using Norplant implants. Whether Norplant is causally related to these symptoms is not yet clear. If a client's headaches can be explained by causes other than Norplant and if headache symptoms are not severe, it may not be necessary to perform a fundoscopic exam.

Breast tenderness. This side effect may occur in some women. Recommended treatments include Vitamin E (600 units/day), tamoxifen (20 mg/day), and danazol (200 mg/day).

Weight gain. Although weight gain is usually due to other causes, weight gain may accompany Norplant use. Occasionally, women decide to discontinue the Norplant because of weight gain.

Hair loss. Hair loss has been noted in a few women, occasionally necessitating Norplant removal.

Acne. Acne has been a problem for some women on Norplant. Usually it is possible to manage acne without removing the implants.

Table 14:4 Common side effects in Norplant users

Side effect	Norplant users
Headaches	16.7-18.5
Breast tenderness	6.2-6.8
Nervousness	6.2-6.8
Dizziness	5.6-8.1
Nausea	5.1-7.7
Acne	4.5-7.2
Dermatitis	3.8-8.2
Breast discharge	3.5-5.1
Change in appetite	3.5-6.2
Weight gain	3.3-6.2
Ovarian enlargement	3.1-11.6
Hair growth or loss	1.8-2.6

Suitability Test. "Should I prescribe a minipill containing levonorgestrel to a woman for several months to see if she is going to tolerate Norplant?" This question is asked repeatedly at Norplant training sessions. Several side effects that could potentially lead to Norplant removal might be anticipated if a woman underwent a suitability test by using a levonorgestrel progestin-only pill for 1 or 2 months before Norplant insertion. Possible indications for using a suitability test for Norplant include a past history of, or extreme patient concern about, the following problems:

- Acne
- Weight gain
- Severe headaches
- Depression
- Allergy to levonorgestrel

Unfortunately, changes in the menstrual cycle that a Norplant user might experience are unlikely to show up with a suitability test. Moreover, the delay in inserting Norplant because of the suitability test means that the woman would be using a less effective contraceptive for a while. Testing a woman with several injections of Depo-Provera would make no sense at all as the hormones and the fluctuations in hormone levels in the serum are completely different.

INSTRUCTIONS FOR USING NORPLANT IMPLANTS

If inserted in the first 7 days of a menstrual cycle, Norplant is effective immediately. No back-up method is necessary. If Norplant has been inserted more than 7 days after your period starts, use a back-up method contraceptive if you have intercourse during the first 24 hours after Norplant insertion.

You are using a very effective contraceptive. Your six implants release levonorgestrel, a hormone-like progesterone that your ovaries produce. Levonorgestrel is the same hormone millions of women take each month in different kinds of birth control pills. You are receiving very low amounts of levonorgestrel constantly. Your contraceptive is

very safe and remains effective for 5 years, at which point it should be removed. You may want to get a new set of implants at that time.

You may have your implants removed at any time. The procedure for Norplant removal takes a bit longer than insertion and may require two visits. The contraceptive effects of Norplant end as soon as the implants are removed. Here is some additional information that might help you:

1. Norplant is one of the most effective contraceptives available. Only about 1 in 1,000 women who use the method will become pregnant in the first year. This pregnancy rate is lower than for the pill or IUD. In the first 2 years of use, Norplant is about as effective as female sterilization. Women who weigh more than 70 kg (154 pounds) may have higher pregnancy rates than those who weigh less.
2. Norplant becomes effective within 24 hours of insertion.
3. If you have pain after insertion, return to see your clinician. You might need antibiotics for an infection. Try to avoid direct pressure on the insertion area for a few days. After the incision has healed, you may touch the skin over the implants. The soft, flexible implants cannot break inside your body, so you should not be concerned about putting pressure on the area.
4. **The Norplant implants may cause you to have irregular bleeding** or more days of bleeding. However, if you have an increased number of days of bleeding, the amount of blood you lose is rarely enough to produce anemia. In fact, you will probably tend to lose less menstrual blood than you did before starting Norplant. A follow-up visit is recommended if you experience heavy bleeding.
5. The hormone levels in Norplant are very low. They are so low that there is very little buildup of the lining of your uterus. This means that there is very little lining to shed and you will notice very light periods or no periods at all. Your bleeding may be irregular. Generally, the amount of blood

loss is less than before Norplant implants are inserted, and some women become concerned when they have no bleeding at all while using Norplant. There is no harm to your health if you do not get your period. If you want to make sure you are not pregnant, you may return to the clinic for a pregnancy test, but you will probably not be pregnant. In some women, menstrual bleeding becomes more regular after implants have been in place for 9 to 12 months.

6. Most women do not have major problems with Norplant. Common side effects noted by women using implants include headaches, nervousness, nausea, dizziness, rash, acne, changes in appetite, weight gain, breast tenderness, hirsutism, and hair loss. Although ovarian cysts sometimes occur in Norplant users, they usually disappear on their own. Surgery is considered if a cyst remains beyond 10 weeks. Several other problems noted by women using Norplant may possibly be caused by the implant: breast discharge, inflammation of the mouth of the womb (cervicitis), mood change, depression, general malaise, weight loss, hypertension, and itching.
7. If you may be at risk for infection of the virus that causes AIDS (the human immunodeficiency virus, or HIV) or any other sexually transmitted infection, continue to use condoms throughout the time you use implants.
8. If you are seen by a clinician for a medical problem, mention that you are using Norplant implants.
9. **Replace the Norplant implants at the end of 5 years**; effectiveness decreases after this time. A new set of implants can be inserted when the old set is removed.
10. Return to your clinician if you have any questions, and watch for the following signs of potential problems:

Norplant Warning Signs

Caution

- Severe lower abdominal pain (ectopic pregnancy is rare but can occur)
- Heavy vaginal bleeding
- Arm pain
- Pus or bleeding at the insertion site (these may be signs of infection)
- Expulsion of an implant
- Delayed menstrual periods after a long interval of regular periods
- Migraine headaches, repeated very painful headaches, or blurred vision

Avoid bumping the area where your Norplant inplants were inserted, and keep this area dry for several days after insertion.

COMMONLY ASKED QUESTIONS ABOUT NORPLANT IMPLANTS

1. *In what situations might Norplant implants be a better choice than the injectable contraceptive Depo-Provera?*

Norplant might be a better option than Depo-Provera when a woman has the following concerns:

- Weight gain is a major concern.
- The woman would have difficulty returning every 3 months for an injection.
- She fears repeated shots.
- When the method is discontinued, the client will want to become pregnant right away. This consideration is particularly important for women in their late reproductive years who want contraception now but will want to become pregnant right away after discontinuing contraception.

- When she needs a very effective reversible contraceptive for a long period of time. Some women have situations that contraindicate pregnancy, such as use of Accutane for a year or more, long-term use of anticoagulants, or chemotherapy for cancer.
- When a decrease in high-density lipoprotein cholesterol would be unacceptable.

2. *Can anything be done for a woman who has persistent bleeding while using Norplant?*

The problem is usually an atrophic endometrium. Chronic spotting can be controlled temporarily by having the woman take OCs for a while, which would stimulate the endometrium for 3 weeks and then remove stimulation for 1 week. Cycle your patient for several months. The additional hormones should not be a problem for most women if you use low-dose OCs or a low dose of conjugated estrogens, either ethinyl estradiol or estradiol.

Explain to the woman experiencing this annoying side effect that repeating the use of these extra hormones would not be harmful, that the amount of blood loss is probably less than she would have with the persistent bleeding rather than more; that she can have sexual intercourse in spite of the spotting; and that you would be happy to do an hematocrit to reassure her she is not anemic. Keep in mind that she could have an unrelated problem such as a chlamydia infection, a fibroid, or a cervical infection.

PROVIDING DEPO-PROVERA (DMPA)

The World Health Organization makes the reassuring statement: "In summary, DMPA and NET-EN (norethindrone enanthate) appear to be acceptable methods of fertility regulation. Clinical evidence from more than 15 years of use as contraceptive agents shows no additional, and possibly fewer, adverse effects than are found with other hormonal methods of contraception. Studies thus far have not shown any serious short- or long-term effects of DMPA or NET-EN."[34] There are a few precautions to the use of Norplant implants. These are noted in Table 14:2.

Toxicologic studies of DMPA in beagle dogs showed an increase in mammary gland tumors, some of which became malignant.[12] These studies have raised concern about the possibility of breast cancer in women using DMPA. Several studies in the United States and elsewhere have found no effect in humans.[13,33] In a New Zealand study, 891 women with newly diagnosed breast cancer were compared with 1,864 women selected at random.[24] Women were interviewed by telephone about their past use of contraceptives and any risk factors for breast cancer. The overall relative risk of breast cancer associated with any use of DMPA was 1.0 (in other words, no increased risk relative to non-users). In women aged 25 to 34 years, the relative risk was 2.0. The risk was greatest among women who used the drug for 6 years or longer. This study suggests that DMPA may accelerate the presentation of breast cancer in young women, perhaps by acting as a promoter in the late stages of carcinogenesis.[24] A World Health Organization collaborative study failed to demonstrate a significantly increased risk for either breast cancer or cervical cancer among women using DMPA.[35,36]

DMPA is usually provided from vials containing 150 mg of DMPA in each 1 cc of solution. DMPA produced in the United States is labeled for a 3-year shelf-life. DMPA made in Belgium has a 5-year shelf-life. The U.S. Agency for International Development expected that the U.S. Food and Drug Administration (FDA) would approve a 3-year sherunlf-life labeling by the time it started purchasing DMPA.[25] Deep intramuscular injections may be made into the deltoid or the gluteus maximus muscles. Injections into the deltoid may be less embarrassing, but slightly more painful. The needle should be 2.5 to 4 cm in length and 21 to 23 gauge; both needle and syringe should be sterile.[34] The area of the injection should NOT be massaged because this may lower the effectiveness of DMPA. Injections usually are not painful.

Injections are scheduled every 3 months, and are performed by clinicians. In international circles, there has been some discussion of self-administering injections of DMPA. After a woman has received several injections, each 150 mg of DMPA has a contraceptive effect greater than 3 months, which means that the method is forgiving of

the woman who returns late for her injection. Some programs will provide injections of DMPA up to 4 weeks late; women are informed that pregnancies are rare but may occur. When a woman does appear late for her shot, stress the importance of returning on time for injections in the future. Try to find out why a woman is late for injections. Her reasons may include a fear of cancer, changes in the pattern of menstrual bleeding, other side effects, cost of injections, time lost coming to the clinic, or partner or family disapproval of the method. Deal with these barriers sympathetically and try to help your client to overcome them. Satisfaction with this method may increase if clients are told to anticipate menstrual irregularity during the first year and an increasing likelihood of amenorrhea in subsequent years.

MANAGING DEPO-PROVERA PROBLEMS AND FOLLOW-UP

At every 3-month follow-up visit, ask about weight gain and any problems or concerns a woman may have, the date of her last menstrual period, and her risk for HIV infection and other STIs. Measure her weight and blood pressure. Use a simple flow chart to document a history of depression, severe headaches, and breast tenderness. In one of the largest studies of DMPA (3,875 users), headaches were noted in 17.1% of users, nervousness in 10.8%, decreased libido in 5.4%, breast discomfort in 2.7%, and depression in 1.7%.[27] Weight gain was greater among clinic patients than among private patients who were provided DMPA.[27] If the client appears to have a normal annual examination and is not complaining of unacceptable weight gain or other unacceptable symptoms, she may continue DMPA injections as long as desired. At the annual visit, perform a full evaluation, which includes all that you do at the 3-month intervals plus a complete exam. You will have an opportunity to discuss a number of subjects.

MENSTRUAL CHANGES

Women need to be informed in advance of the changes that will occur in their menstrual cycles. Do not underestimate the effect of changes in bleeding; they are the major reason many women discontinue this method. Spotting or breakthrough bleeding may be managed most easily in a family planning clinic by offering women a cycle or so of OCs. Five days of pills could be enough, but it may need to be repeated. Inform women that the irregular bleeding may return. Amenorrhea will increase over time and is not harmful.

ALLERGIC REACTIONS

The U.S. Physicians' Desk Reference (PDR) notes that anaphylactic and anaphylactoid reactions may occur immediately following Depo-Provera injections. Fortunately, severe anaphylactic reactions to DMPA are rare. However, since DMPA is irretrievable once injected, ask the client to wait a half hour before leaving the clinic. You should have on hand emergency medications such as epinephrine, steroids, and diphenhydramine.

INSTRUCTIONS FOR USING DEPO-PROVERA

You have chosen a very effective method of birth control: an injection every 3 months of Depo-Provera. Birth control shots are used by more than 6 million women around the world, and Depo-Provera is the contraceptive most commonly used for these shots. If you wish to get pregnant, discontinue birth control shots several months before you plan to conceive. The following information may help you use Depo-Provera:

1. Use an additional contraceptive method for 2 weeks after your first injection. This is not necessary if the first shot is given during the first 5 days after the beginning of a normal menstrual period.

2. If you may be at risk for infection with the virus that causes AIDS (human immunodeficiency virus, or HIV) or any other sexually transmitted infection, continue to use condoms throughout the time you use Depo-Provera.
3. Return to the clinic every 3 months for another injection.
4. Depo-Provera tends to make a woman's periods less regular, and spotting between periods is fairly common. Some women stop having periods completely. If your pattern of bleeding concerns you, return to the clinic to get a blood test for anemia, to rule out the possibility of a pregnancy, or to rule out the possibility of infection.
5. Weight gain is common in users of Depo-Provera. You will have to pay close attention to avoiding excessive calories if you want to avoid this side effect.
6. See your clinician if you develop any problems.

Depro-Provera Warning Signals

Caution

- Weight gain
- Headaches
- Heavy bleeding
- Depression
- Frequent urination

Contact us if you develop any of the above problems.

COMMONLY ASKED QUESTIONS ABOUT DEPO-PROVERA

1. *In what situations might Depo-Provera injections be a better choice for a woman than Norplant implants?*

   Depo-Provera might be more acceptable or a wiser choice than Norplant implants for the woman who

   - Is very concerned about a minor surgical procedure
   - Has a history of sickle cell disease or of seizures, both of which may actually be improved by DMPA[14]
   - Is taking a medication that markedly increases production of liver enzymes, which speed up the breakdown of levonorgestrel (the hormone elaborated by Norplant implants); these drugs include phenobarbital, phenytoin (Dilantin), primidone, carbamazepine, and phenylbutazone
   - Needs highly effective contraception for just a *few months* (For example, a tubal sterilization or vasectomy may be scheduled; she may be receiving rubella immunization; or she may be using a medication like Accutane (for acne), which is known to produce severe defects in babies if taken by a pregnant woman; or she may be taking anticoagulants or valproic acid.)
   - Needs *only a year* of extremely effective contraception (For example, she may have recently had a molar pregnancy and must not become pregnant for 1 year)
   - Has a preference for receiving medications by injection
   - Wants to keep all information about contraceptive use from her partner (for example, an abusive husband who does not want her to use contraception)

2. *Can a woman who is breastfeeding her baby receive Depo-Provera injections?*

Yes, this is an excellent option for breastfeeding mothers. Postpartum bleeding may be somewhat less predictable if DMPA is given immediately postpartum.

3. *Why is a method that was considered "bad" 10 years ago by the U.S. FDA now a good method?*

It has always been a good method. By the time Depo-Provera was approved in the United States, it was already being used by 8 to 9 million women throughout the world, in over 90 countries that had approved Depo-Provera.

4. *What is the most important difference between Depo-Provera (DMPA) and norethindrone enanthate (NET-EN) injections?*

NET-EN injections are injections of norethindrone in an oily base given at 2 month intervals for the first 6 months of use, after which injections are every 2 to 3 months.[9] DMPA is given every 3 months. Other countries also have injections containing both an estrogen and a progestin.

It is important that the woman using NET-EN every 3 months *not be late* for her injection. That 3-month interval should not be exceeded or pregnancy rates will increase. Depo-Provera is more forgiving of the woman who is late for her injection.

PROVIDING PROGESTIN-ONLY PILLS (Minipills)

Because few women use minipills, large-scale studies that document their benefits and side effects have not been conducted. In general, progestin-only pills have lower effectiveness, more breakthrough bleeding, and fewer noncontraceptive benefits than do combined OCs.

Most of the health benefits of progestin-only pills are probably similar to those of combined estrogen-progestin pills: decreased menstrual cramps or pain, less heavy bleeding, a shorter period, decreased premenstrual syndrome symptoms, and decreased breast tenderness. In theory, the thick, less penetrable cervical mucus in women taking progestin-only pills should decrease the risk of PID.

Progestin-only pills should theoretically be safer than combined pills. Progestin-only pills have not been shown to increase the risk of either cardiovascular complications or cancer and are less likely to cause headaches, blood pressure elevation, depression, and other side effects than are higher dose combined OCs.[32] However, the FDA-required class labeling in the package insert for progestin-only pills does not suggest different contraindications for minipills than for combined pills. The authors propose that contraindications be replaced with the precautions noted in Table 14:2.

Progestin-only pills are not the best choice for women who are not organized enough to take a pill every single day.[7] Missing one or two progestin-only pills is more likely to lead to a pregnancy than is missing one or two combined OCs.

MANAGING MINIPILL PROBLEMS AND FOLLOW-UP

The most important problems with progestin-only pills relate to the patterns of bleeding. Many problems can be managed much as they are for women using Norplant implants or Depo-Provera. If the woman has increased days of light or heavy bleeding, spotting, or amenorrhea, first rule out pregnancy. If she is not pregnant, counsel her, switch to a combined OC, use supplemental estrogen (in the form of conjugated estrogens, such as 17-B estradiol or ethinyl estradiol), or use prostaglandin inhibitors.

INSTRUCTIONS FOR USING MINIPILLS

1. Have on hand a back-up birth control method such as foam, spermicidal tablets or suppositories, condoms, or a diaphragm. You will need to use your back-up method:

- While you are waiting to start progestin-only pills or minipills
- During your first cycle on minipills

- If you miss a minipill, use a back-up method until you restart or until your next period

Progestin-only pills are very low dose contraceptives. Your margin of error is not great. Do not count on this method unless you will be able to take pills every single day. Try to take your minipills at the same time every day. Some women use a back-up method at all times to increase the effectiveness of this approach to birth control. (See the questions at the end of these instructions for more on back-up contraceptives while on minipills.)

2. Swallow 1 pill each day until you finish your pill pack. Then start your new pack the next day. Never miss a day. The evening meal may be the best time to take progestin-only pills.

3. If you miss 1 minipill, take it (yesterday's minipill) as soon as you remember. Also take today's minipill at the regular time even if that means taking 2 pills in 1 day. If you are more than 3 hours late taking a minipill, use your back-up birth control method for the next 48 hours (2 days).

4. If you miss 2 or more minipills in a row, there is an increased chance you could become pregnant. Immediately start using your back-up method. Restart your minipills right away and double up for 2 days. If your menstrual period does not begin within 4 to 6 weeks, see your clinician for an exam and a pregnancy test.

5. Keep track of your periods while you take minipills. If you have more than 45 days with no period, you may want to see your clinician for an exam and pregnancy test.

6. If you have spotting or bleeding between periods, keep taking your minipills on schedule. If your bleeding is very heavy or if you have cramps, pain, or fever, see your clinician. Your bleeding may be caused by infection. In most cases, bleeding is not serious and will often stop after a few days. Bleeding is especially likely if you have missed 1 or more minipills. Bleeding is common during the first few months a woman takes minipills.

7. If you become ill with vomiting, severe diarrhea, or both, use your back-up method of birth control along with your minipills until 48 hours (2 days) after your illness is over. Using your back-up method will give you extra protection in case your illness or the medication you take for that illness interferes with minipill effectiveness.

8. If you decide you want to become pregnant, plan to stop using minipills and change to another method of birth control, such as condoms, for 2 or 3 months. Once you are off minipills, your natural cycle should be reestablished. Your clinician will be able to determine your pregnancy due date more accurately if you have at least two natural menstrual periods before you become pregnant.

9. Stop minipills anytime you want, even in the middle of a pill pack. Remember, though, that protection from the minipill does not last after you stop. Begin using another method the very next day.

10. If you may be at risk for infection with the virus that causes AIDS (human immunodeficiency virus, or HIV) or any other sexually transmitted infection, continue to use condoms throughout the time you use minipills.

11. See your clinician regularly for routine checkups. Be sure to have a blood pressure check, Pap smear, breast exam, and pelvic exam.

12. See your clinician right away if you have severe lower abdominal pain while using minipills.

Progestin-Only Pills (Minipills) Warning Signals

Caution

- Abdominal pain—May be due to an ovarian cyst or an ectopic pregnancy. (Don't stop pills but contact us right away)
- Pill taken late—Even if only 3 hours late, use a back-up contraceptive for the next 2 days. Be careful to take the minipill ON TIME.

Commonly Asked Questions about Minipills

1. *What effect do minipills have on ovulation?*

Women taking the progestin-only pills will have one of three patterns: (1) they may ovulate every month, and their periods tend to be quite regular, (2) they may never ovulate, in which case their periods tend to be very irregular and they may go months without any bleeding, and (3) they may ovulate some months and not others, in which case their periods are also irregular.

2. *During the first cycle of minipills, are back-up contraceptives essential?*

No, whether or not a woman ovulates the first month on minipills, the production of a thick cervical mucus starts immediately and continues as long as minipills are taken every day at about the same time.

3. *During the first cycle of minipills, are back-up contraceptives wise?*

Perhaps. Minipills may be forgotten or taken late during that first cycle. Mistakes are more common the first month on any method of birth control.

4. *Which women might benefit most by using a back-up contraceptive while on minipills?*

Women who might be encouraged to use a back-up contraceptive while taking minipills include those who are ?

- In the first cycle (just to make sure pills are remembered and tolerated well)
- Late in taking a minipill (they should use a back-up contraceptive until back on schedule)
- Very regular in their menstrual cycles (e.g., every 28 days)—this is presumptive evidence that women are ovulating and might make them lean toward using a back-up contraceptive
- At any risk for HIV infection or STIs—they should use condoms consistently

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